A RESOLUTION OF THE MAYOR AND COUNCIL OF THE TOWN OF FOREST HEIGHTS (THE "TOWN") ADOPTING A TOWN PUBLIC ACCESS TO AUTOMATED EXTERNAL DEFIBRILLATORS ("AED") PROGRAM ALONG WITH CERTAIN SAFETY POLICIES AND PROCEDURES

Introduced By: Mayor Habeeb-Ullah Muhammad

WHEREAS, automated external defibrillator devices have been demonstrated to be safe and effective, even when used by lay people, since the devices are designed not to allow a user to administer a shock until after the device has analyzed a victim's heart rhythm and determined that an electric shock is required; and

WHEREAS, once a victim has suffered a cardiac arrest, every minute that passes before returning the heart to a normal rhythm decreases the chance of survival by 10 percent; and

WHEREAS, in an effort to simplify the Maryland Public Access AED regulations to make them as user-friendly as possible while still maintaining the necessary safeguards that are a key part of the Program, the Maryland Public Access Automated External Defibrillator Regulations (COMAR 30.06.01-05) were revised, and the newly revised regulations became effective on January 7, 2013; and

WHEREAS, the Mayor and Town Council find that participation in the Maryland Public Access AED Program and the use of AED's do not require medical supervision or a prescription, and do not require a fee to participate; however AED's must be properly maintained and certain reporting requirements must be observed while the Program is being provided; and

WHEREAS, the Mayor and Town Council unanimously passed Resolution 27-18 on May 7, 2018 authorizing the purchase of three (3) AED's to be installed at the Municipal Building; and

WHEREAS, the Mayor and Town Council further finds that it is in the best interest of the Town and will promote the health, safety and welfare of its residents to adopt, support and promote participation in the Maryland Public Access AED Program and provide AED's for use in the Town's Municipal Building.

NOW THEREFORE BE IT RESOLVED, that the Town Council hereby approves and adopts the following:

TOWN AUTOMATED EXTERNAL DEFIBRILLATORS ("AED") PROGRAM POLICY

SECTION I - Purpose

This Policy describes the Town's Public Access to Automated External Defibrillators ("AED") Program Safety Policies and Procedures. The purpose of the Policy is to establish guidelines for

the use, training and maintenance of AEDs as provided by the Town of Forest Heights in compliance with State law.

SECTION II – Applicability

This Policy applies to all Town employees and officials.

SECTION III - General Policy

It is the policy of the Town to provide Automated External Defibrillators (AED's) that are accessible to employees in the event that an employee encounters an individual who is experiencing sudden cardiac arrest. Town employees and officials are encouraged to be trained on the use of Town AED's.

SECTION IV - The Maryland Public Access AED Program

The Mayor and Town Council intends to comply with all relevant State laws, regulations, and with the guidelines of the Maryland Institute for Emergency Medical Services Systems. Maryland Institute for Emergency Medical Services Systems (MIEMSS) provides the public with information about Maryland's Public Access Automated External Defibrillator (AED) Program available on-line at http://www.miemss.org. The Maryland Public Access AED Program permits a business, organization, or municipal corporation, which meets certain requirements, to make automated external defibrillators (AED's) available for individuals suffering sudden cardiac arrest on the Town's premises. The Town may establish an AED program at multiple sites or buildings under one program.

A certificate issued by MIEMSS to a registered entity is effective for three years if compliance with the program requirements is maintained. Prior to setting up and commencing the Town's AED program, the Chief of Police shall obtain the proper registration with MIEMSS.

The Public Access AED Program regulations, adopted by reference herein and found in Appendix 1 hereof, are available at the Code of Maryland Regulations (COMAR) website at http://www.dsd.state.md.us/comar/subtitle_chapters/30_Chapters.aspx#Subtitle06. Should any discrepancies exist between this policy and the text of COMAR regulations, the COMAR regulations are binding. Entities operating AEDs without a valid certificate of authorization or renewal are in violation of Maryland State law.

SECTION V - Program Requirements

The following is a list of the requirements that must be maintained in order to participate in the Maryland Public Access AED Program:

A. AED Coordinator: The Mayor shall designate an AED Program Coordinator who is responsible for implementing and administering the program. Responsibilities include maintaining necessary records and documentation, providing information regarding the AED to

all employees or volunteers at a facility, reporting suspected cardiac arrest and/or use of the AED to MIEMSS, facilitating MIEMSS required monthly inspection and any manufacturer recommended maintenance, and other associated program tasks for all sites associated with a registered Public Access AED Program.

- **B.** Training: The Town Administrator and the Police Chief shall have the AED Coordinator as well as individuals who are expected to operate the AED complete CPR and AED training and subsequent refresher training in accordance with their training course requirements that at a minimum includes content consistent with the recommendations for layperson CPR and AED training in the most current publication of the American Heart Association Guidelines for CPR and Emergency Cardiovascular Care. The AED Coordinator shall ensure that every authorized facility meets the requirements noted.
- **C. AED Placement:** AED's shall be placed in locations which are visible and readily accessible to any person willing to operate the AED in the event of a suspected cardiac arrest. AEDs should never be kept locked or restricted from use by anyone on the premises. Signage indicating the location of the AED(s) on the premises shall also be posted by the AED Coordinator.
- **D. Registration:** Before participating in the Maryland Public Access AED Program, the Chief of Police or his designee shall apply online at www.marylandaedregistry.com. MIEMSS will notify the closest jurisdictional emergency medical services (EMS) operational program and 9-1-1 center of all AED sites registered with MIEMSS.
- **E. Links to 911:** It is essential to notify "9-1-1" *immediately* when a sudden cardiac arrest occurs at an AED site. Therefore each AED site must have an effective means of communicating with "9-1-1," ideally a telephone. In situations when no telephone is available, another means of immediate notification to "9-1-1" should be available, e.g., a two-way radio contacting the facility's switchboard operator who dials "9-1-1."
- **F. Equipment and Maintenance:** Because most reported AED malfunctions result from failure to perform user-based maintenance of the AED, it is required that the Town adhere to the AED manufacturer's guidelines for maintenance, inspection, and repair of AEDs. This includes monthly inspection of the AED and associated equipment, restocking of equipment as needed, replacement of batteries and electrodes as needed, and other necessary procedures. It is required that this equipment list be kept with each AED monthly inspection record (form located in Appendix A of the MIEMSS publication).

Required Equipment (Keep with AED at All Times)

- 2 sets of defibrillator chest pads (electrodes). It is strongly recommended that facilities with children under the age of 8 years include pediatric electrodes as well as adult pads.
- Disposable gloves.
- 1 extra battery set, if the AED uses replaceable batteries other than long life lithium batteries.
- Cables (if your AED has removable cables),

- Maryland Public Access AED Report Forms for Cardiac Arrests (forms located in referenced Appendix A or on the MIEMSS webpage), and
- A ready-to-use AED should be kept in an unlocked case with no visible signs of damage that would interfere with its use.
- **G. Reporting:** If there is a suspected cardiac arrest at a location that is registered in the Maryland Public Access AED Program, the Maryland Public Access AED Report form for Cardiac Arrests and if possible the AED event download summary should be completed and faxed or emailed to MIEMSS as soon as possible but not longer than 48 hours following the incident, even if the AED was not used. The form and instructions for completion are located in Appendix A of a document entitled "Maryland Public Access AED Program," published by MIEMSS and available from the MIEMSS Office of Special Programs (410) 706-4740. Forms may also be accessed from the MIEMSS webpage at www.miemss.org.
- **H. AED Malfunction:** If there is a suspected malfunction of the AED, a report must be filed with the FDA and a copy of the report must be sent to MIEMSS. Information on device malfunction reporting may be found at the following FDA website: http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm
- **I.** Compliance: Entities participating in the AED Program are expected to maintain all Program requirements. MIEMSS may perform a compliance review upon information that an entity has failed to comply with Program requirements. Therefore, it is essential that records are efficiently maintained on MIEMSS forms (included in Appendix A of "Maryland Public Access AED Program" publication) and are immediately available should inspection become necessary.
- J. Application Process: The designated AED Coordinator shall apply for the Town to participate in the Maryland Public Access AED Program online www.marylandaedregistry.com. Instructions are provided in Appendix A of "Maryland Public Access AED Program" publication referenced above. AED Program applicants meeting the Program requirements will be approved by the EMS Board and issued a certificate valid f r a period of three (3) years after which time program applicants must reapply. Applicants not meeting the requirements will be denied and will be given a written explanation stating the reason for denial. Applicants that have been denied may re-apply, or may file an appeal within 20 days of receipt of the EMS Board's decision stating the reason that the Board should reconsider its decision. Applicants filing an appeal will be granted a hearing before the EMS Board or the Office of Administrative Hearings.
- **K.** Assistance: For further assistance from the State, the AED Program Coordinator or other authorized staff may contact:

Ms. Ann McCaslin Program Administrator, MIEMSS AED Program 301 Bay Street, Suite 306 Easton. MD 21601 Phone 410-822-1799

Fax: 410-822-0861

Email: amccaslin@miemss.org

SECTION VI - RESPONSIBILITIES

A. The Mayor, Town Administrator and supervisors shall ensure that employees are permitted to attend AED training and to advise employees where AED's are located.

- B. Employees shall:
- 1. Attend AED training if practical and adhere to this Policy;
- 2. Use an AED responsibly.
- C. AED Program Coordinator shall:
- 1. Provide/schedule periodic training;
- 2. Ensure that all Town-owned AED's are properly maintained;
- 3. Ensure this Resolution, as amended from time to time, and any other written instructional materials on this subject contain accurate and updated information at all times.

SECTION VII - Maryland Public Access AED Protocol

All personnel expected to operate an AED at a registered Town facility shall utilize the AED in accordance with their training. When an individual's training conflicts with the auditory and visual prompts of the device, the individual shall follow the auditory and visual prompts.

SECTION VIII - Maryland AED Registry Instructions

A. Maryland's AED law requires non-exempt organizations, such as the Town, with AEDs to register with MIEMSS and maintain a current certificate in order to have AED's on site. To register the AED(s) with MIEMSS, the Town's AED Program Coordinator shall go to www.marylandaedregistry.com and enter the required information into the Maryland AED registry. In order to do so, the authorized person will be required to set up a username and password.

- B. It is recommended that the registrant use Google Chrome or Mozilla Firefox for the web browser and not Internet Explorer for best results. Upon creation of the account the user will receive an automated email asking for verification of the information entered after which he or she will be able to add specific program information. In addition to the site location information for all AEDs and sites under the program, the AED Program Coordinator shall provide the make and model of the AED(s) and serial number(s), and the battery and electrode expiration dates.
- C. Upon completion the AED Program Coordinator will be automatically issued a new certificate by email valid for an additional 3 years. The Maryland AED Registry will automatically send

monthly reminders to update the Registry with any changes or new information as well as when AED batteries and electrodes are nearing expiration.

D. The information entered into the Maryland AED Registry will be included in the National AED Registry™ and will be made available to the EMS 9-1-1 dispatch center in the community in the event there is a cardiac arrest at a Town site. Currently, MIEMSS will only accept electronic AED application submissions to the Maryland AED Registry. For assistance, one may call 410-822-1799 or email amccaslin@miemss.org.

SECTION IX - Procedures

A. Use of Automatic External Defibrillators

The key to survival following sudden cardiac arrest ("SCA") is the speed of response. When responding to a victim who may be in SCA and in need of assistance, the primary objective is to ensure that medical personnel are en route to the scene as soon as possible. The following steps are recommended guidelines to follow in SCA emergencies:

- 1. Call, or ask someone to call, 911, preferably from a cell phone so that the phone can be taken to the scene. Ask for assistance in keeping area around the victim clear and keep crowds away.
- 2. Approach the victim and assess responsiveness: Tap shoulders and shout, "Are you OK?"
- 3. Dispatch will ask a series of questions and will activate emergency medical services.
- 4. Check ABC's (Airway, Breathing and Circulation).
 - a. Assess airway.
 - b. Perform head-tilt; chin lift to open the airway.
 - c. Assess Breathing. Look, Listen and Feel. If breathing is absent, use the barrier device attached to the AED case to deliver two rescue breaths.
 - d. Place AED near head of patient on same side as the rescuer.
 - e. Turn on the AED by simply opening the lid or pressing the appropriate button.
 - f. Follow AED verbal and visual prompts.
 - g. Bare and prepare the chest (cut or tear away clothing if necessary)
 - h. Follow AED verbal and visual prompts.
 - i. Apply electrodes (follow drawings on pads).
 - j. Allow AED to analyze.
 - k. If indicated, deliver shock by pressing the button.
 - 1. Continue care per AED instructions.
 - m. Await EMS arrival.

B. Training

Annual training shall be offered by a certified trainer and will include the following:

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- 1. The proper use, maintenance and periodic inspection of the AED;
- 2. The importance of CPR, defibrillation, advance life support, adequate airway care and the internal emergency response system (if applicable).
- 3. An overview of the local emergency medical services (EMS) system, including 911 access and interaction with EMS personnel.
- 4. Assessment of the unconscious patient is to include evaluation of airway, breathing and circulation to determine if a cardiac arrest has occurred and the appropriateness of applying and activating the AED.
- 5. Information relating to defibrillator safety precautions enabling someone to administer a shock without jeopardizing the safety of the patient, the authorized individual or other nearby persons.
- 6. Recognition that an electrical shock has been delivered to the patient and that the defibrillator is no longer charged.
- 7. Rapid, accurate assessment of the patient's post-shock status to determine if further activation of the AED is necessary.
- 8. Authorized individual's responsibility for continuation of care such as applying repeated shocks if necessary, accompanying the person to the hospital, or waiting until the arrival of more medically qualified personnel.
- C. Maintenance of Automatic External Defibrillator

The AED typically performs automatic tests daily, weekly and monthly. If the AED detects a problem during an automatic test that requires immediate service, such as low battery, it activates an intermittent audible alarm. Monthly inspections of the AED's will be performed by Town AED Program Coordinator. The typical service indicator message (a red X) will appear in the LED square in the upper right-hand corner if the AED detects a problem that requires service. The units typically perform a comprehensive series of analyses and store data within the devices. The units feature Lithium batteries with an internal analysis chip which records daily selftest data and provides charge level data to the onboard diagnostic software. Any problems or concerns with the units shall be reported to the AED Program Coordinator. Each individual AED model may contain operational variations from this section. Please consult the manufacturer's operating instructions.

SECTION X - Good Samaritan Laws

Generally, there is no special duty to involve oneself in an accident or emergency to act as a Good Samaritan. There is no legal requirement that where an accident or injury takes place, a person not involved has to assist or provide medical care to another. However, the law looks to

ensure that where the Good Samaritan decides to provide care or assistance, not only will his or her actions be protected from civil suit.

According to Maryland's Good Samaritan law, a person may not be civilly liable for his or her actions while providing assistance or medical care to another in time of need. To satisfy the requirements of the Good Samaritan Law, a person who is providing assistance or medical care must be at the scene of an accident or emergency, may provide this assistance or medical care before being transported to a medical facility, or if the Good Samaritan is acting on instructions provided by trained personnel. The person may only be found to be civilly liable if he or she acted in a way that was grossly negligent. In other words, if the person acted in a way that was negligent, he or she would still be protected; however, gross negligence is a different standard and assumes that the Good Samaritan was beyond just inexperienced or merely negligent, but he or she may have been reckless or otherwise had little consideration for the person whom he or she was trying to help.

Additionally, the Maryland law requires that a person may also be shielded from civil liability where he or she acted in a reasonable manner, he or she was not compensated for his or her assistance, and once certified or licensed medical professionals or emergency responders arrived to the scene and at the assistance of the injured party, the person withdrew care.

Good Samaritan Laws have been established in all states to mitigate the liability of trained or certain untrained individuals using an AED to attempt to save the life of an individual suffering from sudden cardiac arrest. In addition, in 2000, Congress passed the Cardiac Arrest Survival Act which provides those who acquire and use an AED with protection from liability. The relevant portions of the federal law are as follows:

LIABILITY REGARDING EMERGENCY USE OF AUTOMATED EXTERNAL DEFIBRILLATORS (Excerpt from Public Health Improvement Act of 2000 which includes the Cardiac Arrest Survival Act)

SEC. 248.

- (a) GOOD SAMARITAN PROTECTIONS REGARDING AEDS. —Except as provided in subsection (b), any person who uses or attempts to use an automated external defibrillator device on a victim of a perceived medical emergency is immune from civil liability for any harm resulting from the use or attempted use of such device; and in addition, any person who acquired the device is immune from such liability, if the harm was not due to the failure of such acquirer of the device—
- (1) to notify local emergency response personnel or other appropriate entities of the most recent placement of the device within a reasonable period of time after the device was placed;
- (2) to properly maintain and test the device; or
- (3) to provide appropriate training in the use of the device to an employee or agent of the acquirer when the employee or agent was the person who used the device on the victim, except that such requirement of training does not apply if—

- (A) the employee or agent was not an employee or agent who would have been reasonably expected to use the device; or
- (B) the period of time elapsing between the engagement of the person as an employee or agent and the occurrence of the harm (or between the acquisition of the device and the occurrence of the harm, in any case in which the device was acquired after such engagement of the person) was not a reasonably sufficient period in which to provide the training.

The relevant portions of the state law are as follows:

MD Code, Courts and Judicial Proceedings, § 5-603

§ 5-603. Emergency medical care

In general

- (a) A person described in subsection (b) of this section is not civilly liable for any act or omission in giving any assistance or medical care, if:
 - (1) The act or omission is not one of gross negligence;
 - (2) The assistance or medical care is provided without fee or other compensation; and
 - (3) The assistance or medical care is provided:
 - (i) At the scene of an emergency;
 - (ii) In transit to a medical facility; or
 - (iii) Through communications with personnel providing emergency assistance. Licensed individuals or members of volunteer fire departments, ambulance and rescue squads, or law enforcement agencies
- (b) Subsection (a) of this section applies to the following:
 - (1) An individual who is licensed by this State to provide medical care;
 - (2) A member of any State, county, municipal, or volunteer fire department, ambulance and rescue squad, or law enforcement agency, the National Ski Patrol System, or a corporate fire department responding to a call outside of its corporate premises, if the member:
 - (i) Has completed an American Red Cross course in advanced first aid and has a current card showing that status;
 - (ii) Has completed an equivalent of an American Red Cross course in advanced first aid, as determined by the Secretary of Health;
 - (iii) Is certified or licensed by this State as an emergency medical services provider; or
 - (iv) Is administering medications or treatment approved for use in response to an apparent drug overdose and the member is:
 - 1. Licensed or certified as an emergency medical services provider by the State Emergency Medical Services Board and authorized to administer the medications and treatment under protocols established by the State Emergency Medical Services Board;

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- 2. Certified to administer the medications and treatment under protocols established by the Secretary of Health; or
- 3. Certified to administer the medications and treatment under protocols established by the Maryland State Police Medical Director;
- (3) A volunteer fire department or ambulance and rescue squad whose members have immunity; and
- (4) A corporation when its fire department personnel are immune under item (2) of this subsection.

Reasonable and free assistance or aid

- (c) An individual who is not covered otherwise by this section is not civilly liable for any act or omission in providing assistance or medical aid to a victim at the scene of an emergency, if:
 - (1) The assistance or aid is provided in a reasonably prudent manner;
 - (2) The assistance or aid is provided without fee or other compensation; and
 - (3) The individual relinquishes care of the victim when someone who is licensed or certified by this State to provide medical care or services becomes available to take responsibility. (Emphasis added.)

AND BE IT FURTHER RESOLVED THAT, the Chief of Police and Town Administrator shall ensure that AED Coordinator receives AED and CPR training and the Chief and said Coordinator shall recommend specific locations for AED's and ensure placement of the AED's in a transparent box hung on the wall and out of reach of small children but that the AED's remain unlocked, maintained and accessible to any Good Samaritan/Operator wising to use an AED in an emergency situation.

AND BE IT FURTHER RESOLVED THAT, the Mayor, Chief of Police and/or Town Administrator are hereby authorized to execute documents and take any action necessary to carry out the intent of this Resolution.

AND BE IT ALSO FURTHER RESOLVED, that this Resolution shall take effect from the date of its passage by the Town Council.

PASSED this **O**day of June 2018.

APPROVED: By Resolution of the Town Council of The Town of Forest Heights, Maryland.

ROLL CALL VOTE

MUHAMMAD

KENNEDY II

MCLAURIN

BARNES

HINES

YEA/NAY/ABSTAIN/ABSENT

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| WASHINGTON | <u>Olu</u> |
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| BROWNSON | izu |
| ATTEST: | THE TOWN OF FOREST HEIGHTS, MARYLAND |
| SIGNATURE ON FILE | By: |
| Sherletta Hawkins, Town Clerk | Habeeb-Ullah Muhammad, Mayor |
| | By: SIGNATURE ON FILE Calvin Washington, Council President |
| | CERTIFICATION |
| I, hereby certify, as the duly appointed that on the 6 day of June 2018 wit Resolution 44-18 passed. | ed Town Clerk of the Town of Forest Heights, Maryland, h Aye votes and Nay vote the aforesaid |
| 1 | SIGNATURE ON FILE |
| | Sherletta Hawkins, Town Clerk |
| | |

Appendix 1 (current as of May 2018).

Title 30 MARYLAND INSTITUTE FOR EMERGENCY MEDICAL SERVICES SYSTEMS (MIEMSS)

Subtitle 06 PUBLIC ACCESS AUTOMATED EXTERNAL DEFIBRILLATOR PROGRAM

Chapter 01 Definitions

Authority: Education Article, §13-517, Annotated Code of Maryland

30.06.01.01

.01 Definitions.

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- A. In this subtitle, the following terms have the meanings indicated.
- B. Terms Defined.
- (1) "Automated external defibrillator (AED)" means a medical heart monitor and defibrillator device that:
 - (a) Is cleared for market by the federal Food and Drug Administration;
- (b) Recognizes the presence or absence of ventricular fibrillation or rapid ventricular tachycardia;
- (c) Determines, without intervention by the operator, whether defibrillation should be performed;
 - (d) On determining that defibrillation should be performed, automatically charges; and
 - (e) Either:
 - (i) Requires operator intervention to deliver the electrical impulse, or
 - (ii) Automatically continues with delivery of electrical impulse.
- (2) "Event (code) summary" means the electronic report of an AED operation produced by an AED.
- (3) "Expected operator" means any individual identified by a registered facility to operate an AED at a registered facility
 - (4) "Facility" means an agency, association, corporation, firm, partnership, or other entity.
- (5) "Operate" means to use or attempt to use an AED to defibrillate an individual whether or not any electrical impulse is delivered.
- (6) "Public safety answering point (PSAP)" has the meaning stated in Public Safety Article, §1-301(q), Annotated Code of Maryland.
 - (7) Registered Facility.
- (a) "Registered facility" means an organization, business, association, or agency that meets the requirements of the EMS Board for providing automated external defibrillation.
 - (b) "Registered facility" may include multiple sites.

- (8) "Response" means the removal of the AED from its storage location for the purposes of rendering care whether or not the care is actually rendered.
- (9) "Site" means a building, plant, unit, branch, vehicle, or other ancillary location that is part of or affiliated with a facility.

Chapter 02 Approval of Facilities and Compliance

Authority: Education Article, §13-517, Annotated Code of Maryland

.01 Criteria for Registration of Facilities.

To be eligible for registration, or renewal of registration, to operate an AED under this subtitle, a registered facility shall:

- A. Designate an AED coordinator who shall:
- (1) Have successfully completed CPR and AED Training, and subsequent refresher training, in accordance with their training course requirements that at a minimum includes content consistent with the recommendations for layperson CPR and AED training in the most current publication of the American Heart Association Guidelines for CPR and ECC;
- (2) Be responsible for implementing and administering the AED program at the registered facility; and
- (3) Ensure that monthly safety inspections of all supplemental and AED equipment, including assurance of adequate battery charge, per the manufacturer's guidelines are conducted and maintain written logs of the inspections.
- B. Provide information regarding the operation, maintenance, and location of the registered facility's AEDs to all individuals employed by or volunteering for the registered facility;
- C. Place all AEDs in locations which are visible and readily accessible to any person willing to operate the AED in the event of a cardiac arrest;
- D. Have a telephone or other communication service available at all times at each site at which an AED is operated, for the notification of the public safety answering point;
- E. Submit data or other information concerning the AED program which may be periodically requested by MIEMSS; and
- F. Ensure that expected operators have completed CPR and AED Training, and subsequent refresher training, in accordance with their training course requirements that at a minimum includes content consistent with the recommendations for layperson CPR and AED training in the most current publication of the American Heart Association Guidelines for CPR and ECC.

.02 Protocol.

All personnel who are expected to operate an AED at a registered facility shall utilize the AED in accordance with their training. When an individual's training conflicts with the auditory and visual prompts of the device, the individual shall follow the auditory and visual prompts.

.03 Quality Assurance and Maintenance.

Each registered facility shall:

A. Comply the federal Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992;

B. Maintain:

- (1) The certificate issued by MIEMSS in a place where it is readily available;
- (2) Each AED and all related equipment and supplies in accordance with the standards established by the device manufacturer and the federal Food and Drug Administration;
 - (3) Supplemental equipment with the AED at all times as follows:
 - (a) Two sets of defibrillator chest pads;
 - (b) Disposable gloves; and
 - (c) Maryland Facility AED Report Forms for Cardiac Arrest;

C. Submit:

- (1) A report for each incident of suspected cardiac arrest at the facility on the Maryland Facility AED Report Form for Cardiac Arrests, including, when available, any event (code) summary, recording, or tape created by the AED to MIEMSS, and be available for follow up as necessary; and
- (2) If the AED fails when operated, in addition to submitting the required report to the federal Food and Drug Administration, a copy of the report to MIEMSS; and
- D. Ensure the confidentiality of any medical records maintained by the registered facility as required by law.

30.06.02.04

.04 Application and Registration Process.

- A. A facility seeking registration or renewal of registration shall submit an application and all required documentation to MIEMSS on the form required by MIEMSS.
- B. MIEMSS may make the inspection and require the verification necessary to ensure that an applicant meets the requirements of this chapter, including an inspection of the facility, any sites, equipment, and records.
- C. MIEMSS shall issue a certificate of registration or renewal to a facility that meets the requirements of Regulation .01 of this chapter.
 - D. The certificate of registration or renewal is valid for a period of 3 years.

.05 Denial of Registration.

- A. MIEMSS may deny an application if it finds that the applicant fails to meet the requirements of this chapter.
 - B. Notice of Denial.
- (1) MIEMSS shall issue a written notice of denial to an applicant that includes the reasons for denial.
- (2) The notice shall conform to the requirements of State Government Article, §10-207, Annotated Code of Maryland.
- C. An applicant denied approval may file an appeal with the EMS Board under Regulation .05 of this chapter.
- D. If an applicant does not file a timely appeal under Regulation .05 of this chapter, the decision is final.
 - E. If an application is denied, the applicant may reapply under this chapter.

.06 Compliance.

- A. MIEMSS may initiate a compliance review of a registered facility upon information that the registered facility has failed to comply with this subtitle.
 - B. MIEMSS shall give written notice of the compliance review to the registered facility.
 - C. In the course of its compliance review, MIEMSS may:
 - (1) Inspect all:
 - (a) Sites where the registered facility maintains an AED;

- (b) Records relating to the AED maintained by the facility; and
- (c) Equipment related to the AED; and
- (2) Interview employees of the registered facility regarding the AED program.
- D. If MIEMSS finds that a registered facility has failed to comply with this subtitle, MIEMSS may:
 - (1) Suspend the facility's registration;
 - (2) Revoke the facility's registration;
 - (3) Refuse to renew a facility's registration; or
 - (4) Take other action as appropriate.
- E. Within 30 days after the conclusion of the compliance review, MIEMSS shall provide its findings, decision and any proposed action in writing to the:
 - (1) Registered facility; and
 - (2) EMS Board.
 - F. The report shall:
- (1) Conform to the requirements of State Government Article, §10-207, Annotated Code of Maryland; and
 - (2) Contain the reasons for the decision and the proposed action.
- G. Upon receipt of the report and proposed action, a registered facility may file an appeal with the EMS Board under Regulation .05 of this chapter.
- H. If an applicant does not file a timely appeal under Regulation .05 of this chapter, MIEMSS' proposed decision is final.

.07 Procedure for Appeals.

- A. An applicant or registered facility may appeal a disputed decision by filing a notice of appeal to the EMS Board with the Executive Director of MIEMSS not later than 20 days after receipt of the decision.
- B. The appeal shall state with specificity the reasons why the disputed decision should be modified.

- C. An applicant or registered facility that files an appeal shall be granted a hearing before the:
 - (1) EMS Board; or
- (2) Office of Administrative Hearings, if the Board so elects and notifies the applicant or registered facility.
 - D. An appeal hearing shall be governed by COMAR 28.02.01.
- E. If the hearing is conducted by the Office of Administrative Hearings, COMAR 30.02.06.22 and .23 also apply.
- F. An applicant or registered facility which has participated in a hearing under this regulation may seek judicial review of the EMS Board's final action under State Government Article, §10-222, Annotated Code of Maryland. The EMS Board shall be party to the proceeding.

.08 Confidentiality of Records.

MIEMSS shall maintain the confidentiality of records referred to in this subtitle in accordance with:

- A. Health-General Article, Title 4, Subtitle 3, Annotated Code of Maryland;
- B. Health Occupations Article, Title 1, Subtitle 4, Annotated Code of Maryland; and
- C. General Provisions Article, Title 4, Subtitle 3, Annotated Code of Maryland.